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STUDY PROTOCOL



Early intervention with eye movement desensitisation and reprocessing (EMDR) therapy to reduce the severity of posttraumatic stress symptoms in recent rape victims: study protocol for a randomised controlled trial

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ABSTRACT

Background: It is estimated that more than 40% of rape victims develop a posttraumatic stress disorder (PTSD), a statistic that is relatively high compared to other types of trauma. PTSD can affect the victims' psychological, sexual, and physical health. Therefore, there is an urgent need for early interventions to prevent the onset of PTSD in this target group.

Objective: This randomised controlled trial (RCT) examines the efficacy of early Eye Movement Desensitisation and Reprocessing (EMDR) therapy aimed to reduce the severity of posttraumatic stress symptoms in victims of recent rape.

Methods: Subjects (N = 34) are individuals of 16 years and older who present themselves within 7 days post-rape at one of the four participating Sexual Assault Centres in the Netherlands. The intervention consists of two sessions of EMDR therapy between day 14 and 28 post-rape, while the control group receives treatment as usual, consisting of careful monitoring of stress reactions by a case-manager across two contacts during 1-month post-rape. Baseline assessment, posttreatment assessment and follow-up assessments at 8 and 12-weeks post-rape will be used to assess the development of posttraumatic stress symptoms. In addition, the efficacy of the intervention on psychological and sexual functioning will be determined. Linear mixed model analysis will be used to explore the differences within and between the EMDR group and control group at the various time points.

Conclusions: The results of this RCT may help the dissemination and application of evidence-based preventative treatments for PTSD after rape.

La intervención temprana con la terapia de desensibilización y reprocesamiento por movimiento ocular (EMDR) para la reducción de la severidad de los síntomas de estrés postraumáticos en víctimas recientes de una violación: el protocolo de un ensayo controlado aleatorizado

Antecedentes: Se ha estimado que más del 40% de las víctimas de violación desarrollan un trastorno de estrés postraumático (TEPT), una estadística que es relativamente alta en comparación a otros tipos de trauma. El TEPT puede afectar la salud psicológica, sexual, y física de las víctimas. Por lo tanto, existe una necesidad urgente por intervenciones tempranas para prevenir la aparición de TEPT en este grupo objetivo.

Objetivo: Este ensayo controlado aleatorio (RCT en sus siglas en inglés) examina la eficacia de una terapia temprana de Desensibilización y Reprocesamiento por Movimiento Ocular (EMDR en sus siglas en inglés) orientada a reducir la severidad de los síntomas de estrés postraumáticos en las víctimas recientes de una violación.

Método: Los sujetos (N=34) son individuos de 16 años y más, que se presentan en uno de los cuatro Centros de Agresión Sexual participantes en los Países Bajos dentro de los 7 días posteriores a la violación. La intervención consiste de dos sesiones de terapia EMDR entre el día 14 y 28 luego de la violación, mientras que el grupo control recibe tratamiento habitual, el que consiste en un monitoreo cuidadoso de las reacciones de estrés en dos contactos durante un mes posterior a la violación, a cargo de un encargado del caso. La evaluación inicial (línea base), de post-tratamiento, y de seguimiento a las 8 y 12 semanas posteriores a la violación serán usadas para medir el desarrollo de los síntomas de estrés postraumático. Además, la eficacia de la intervención en el funcionamiento psicológico y sexual será determinada. Los análisis de modelos mixtos lineales serán usados.

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PTSD; rape; sexual assault;
study protocol; RCT

PALABRAS CLAVES

EMDR; intervención
temprana; TEPT; Violación;
Agresión Sexual; protocolo;
RCT

关键词

EMDR; 早期干预; 创伤后应
激障碍; 强奸; 性侵犯; 研
究方案; RCT

HIGHLIGHTS

- Rape victims are at high risk for developing PTSD.
- Research has not yet found effective, evidence-based early post-rape interventions.
- This study examines the effectiveness of EMDR in reducing posttraumatic stress symptoms after rape.
- The RCT examines a variety of psychological problems during three months after rape.

Conclusión: Los resultados de este RCT ayudarían a la difusión y aplicación de los tratamientos preventivos basados en la evidencia para el TEPT luego de una violación.

眼动脱敏和再处理 (EMDR) 早期干预治疗减轻近期遭受强奸受害者的创伤后应激症状的严重程度：随机对照试验的研究方案

背景: 据估计, 超过40%的强奸受害者出现创伤后应激障碍 (PTSD), 这一数据高于其他类型的创伤。PTSD可以影响受害者的身心健康和性健康。因此, 迫切需要早期干预以预防该目标群体中PTSD的发作。

目的: 本随机对照试验 (RCT) 检查早期眼动脱敏和再处理 (EMDR) 治疗的效果, 旨在降低近期强奸受害者PTSD症状的严重程度。

方法: 被试 (N = 34) 是16岁及以上的个体, 他们在遭受强奸后7天内来到荷兰四个性攻击中心之一。干预措施包括在强奸发生后第14天和第28天之间进行两次EMDR治疗, 而对照组照常接受治疗, 包括在强奸后一个月的一位管理人员通过两名联系人监测压力反应。强奸后8周和12周的基线评估, 治疗后评估和随访评估将用于评估创伤后应激症状的发展。另外, 还评估了干预对心理和性功能的有效性。使用线性混合模型分析用于探索EMDR组和对照组在不同时间点的组间和组间差异。

结论: 该RCT的结果可能有助于传播和应用强奸后PTSD的循证预防性治疗。

Victims of rape are at high risk of developing a wide array of psychological problems, including substance abuse, depression, dissociation, sexual disorders, anxiety disorder, and suicidal ideation (Faravelli, Giugni, Salvatori, & Ricca, 2004; Galatzer-Levy, Nickerson, Litz, & Marmar, 2013; Ozer & Weiss, 2003; Tiihonen Möller, Bäckström, Söndergaard, & Helström, 2014; Weaver et al., 2007), as well as feelings of shame and guilt about the assault (Aakvaag et al., 2016). Additionally, rape victims often experience involuntary motor inhibition known as tonic immobility during the assault, which has been linked to the development of psychopathology (Möller, Söndergaard, & Helström, 2017). Most prominently, rape is associated with the development of posttraumatic stress disorder (PTSD), as it has been estimated that 94% of the rape victims suffer from posttraumatic stress symptoms in the immediate aftermath of the event (Rothbaum, Foa, Riggs, Murdock, & Walsh, 1992). Although these reactions typically alleviate over time, the risk of developing PTSD is relatively high compared to other types of traumatic events, with rates up to 47% at three months post-rape (Elklit & Christiansen, 2010; Rothbaum et al., 1992; Tiihonen Möller et al., 2014). PTSD is diagnosed when patients suffer from intrusion symptoms (e.g., intrusive memories), avoidance of trauma-related internal (thoughts and emotions) or external (e.g., people or places) stimuli, negative cognitions and mood (e.g., distorted beliefs regarding blame), and heightened arousal (e.g., reckless behaviour; American Psychiatric Association, 2013) for at least one month. In rape victims, PTSD appears to be a risk factor for revictimization, meaning that those who developed PTSD after being raped are significantly more likely to being raped again, compared to victims who do not develop PTSD (Messman-Moore, Ward, & Brown, 2009). Thus, post-rape psychological problems, including PTSD, present a burden to both the individuals' personal quality of life and the public

health system by affecting their sexual, social, and physical health (Brunello et al., 2001; McFarlane, 2010).

Regarding the treatment of PTSD, meta-analyses (Chen et al., 2014) and treatment guidelines (e.g. American Psychiatric Association, 2017; International Society for Traumatic Stress Studies [ISTSS], 2018; U.S. Department of VA, DoD, 2016; World Health Organization, 2013) recommend the application of Cognitive Behaviour Therapy (CBT) or Eye Movement Desensitisation and Reprocessing (EMDR) Therapy. While the guidelines for PTSD treatment are well defined, at present there is no strong recommendation for evidence-based interventions available for acutely traumatised individuals (ISTSS, 2018). Research that would identify a short-term, cost-effective and easily dispersed post-rape intervention is thus extremely important, particularly given the high risk of developing PTSD sequelae and its significant public health impact (McFarlane, 2010). For this purpose several interventions have been developed (Oosterbaan, Covers, Bicanic, Huntjens, & De Jongh, manuscript submitted for publication). More specifically, four studies report on the efficacy of early intervention in reducing PTSD symptom severity when applied within the first-month post-rape. The first study is a randomised controlled trial (RCT) that investigated the efficacy of three 1-h sessions of prolonged exposure therapy starting within one day post-rape with 137 trauma victims (including 47 rape victims). It was found that posttraumatic stress symptom severity decreased significantly more for the rape victims in the intervention condition than those in the control condition (i.e. assessment-only) after four and 12 weeks (Rothbaum et al., 2012). A second RCT determined the efficacy of one 17-min psycho-education video in reducing posttraumatic stress symptom severity in 140 victims of sexual assault with prior rape history within the first three days post-rape (Resnick et al., 2007). They found a significantly larger reduction in posttraumatic stress symptoms at six months post-rape compared to

the assessment-only control group. However, when this study was replicated in a sample of victims with no prior rape history, no effect was found (Miller, Cranston, Davis, Newman, & Resnick, 2015). Finally, a non-controlled pre-post study on EMDR therapy within three days post-assault reported on the treatment of 17 victims of sexual assault. The results showed a significant reduction in posttraumatic stress symptoms and sexual problems, which remained stable at four weeks and six months after the intervention (Tarquinio, Brennstuhl, Reichenbach, Rydberg, & Tarquinio, 2012). Thus, a limited number of studies with small samples provide preliminary evidence for the efficacy of early interventions following rape in terms of an ameliorating effect on posttraumatic stress symptoms.

Concerning early post-rape intervention, no RCTs using EMDR therapy have been conducted to date. However, in recent years, several RCTs have found early EMDR therapy to be more efficacious in reducing posttraumatic stress symptoms than delayed treatment in victims of earthquakes (Jarero, Artigas, & Luber, 2011), missile attacks (Shapiro & Laub, 2015; Shapiro, Laub, & Rosenblat, 2018), workplace violence (Tarquinio et al., 2016), and traumatised first responders (Jarero, Amaya, Givaudan, & Miranda, 2013). In these studies, the control groups received treatment within one month after the intervention group. Therefore, the long-term effect (at three to six-month follow-ups) of early EMDR therapy is difficult to determine. Still, these preliminary findings underline the relevance of studying early EMDR treatment in rape victims.

1.1. Aims

The aim of the current study is to determine the efficacy of Early EMDR therapy on posttraumatic stress symptoms, psychological and sexual function, and guilt/shame in victims of rape. Our primary hypothesis is that individuals who have very recently been exposed to a rape and who receive Early EMDR therapy would demonstrate significantly less self-reported and clinician-reported posttraumatic stress symptoms at post-treatment and eight and 12-weeks post-rape follow-ups than those who receive treatment as usual. Second, it is hypothesised that victims of rape who receive early EMDR therapy would demonstrate a significantly lower level of psychological and sexual dysfunction, and guilt/shame at posttreatment and both follow-ups than victims who receive treatment as usual. Further, the direct effect of the early EMDR treatment will be examined using ratings of trauma memory vividness and emotionality (see Littel, van Schie, & van den Hout, 2017; Van Veen et al., 2015). It is hypothesised that vividness and emotionality would decrease significantly more between pretreatment, posttreatment, and follow-ups in the victims who receive EMDR than in those who

receive treatment as usual. Finally, this study will examine representation and fragmentation of trauma memory and the extent to which peritraumatic tonic immobility during rape occurs.

2. Methods/design

2.1. Study design

This study is designed as a longitudinal randomized controlled trial (RCT), which allows us to determine the effect of early EMDR on the development of post-traumatic stress symptoms compared to treatment as usual. Subjects will be randomised to either the Early EMDR intervention or the control condition (treatment as usual). Over the course of three months, subjects will be assessed at four time points: pretreatment at two weeks post-rape, posttreatment at one week posttreatment, and follow-ups at 8- weeks and 12-weeks post-rape. A block randomization sequence is computer-generated per participating centre, and the allocation of the participants will be blinded for the trained master level psychology students who conduct the initial and follow-up assessments.

2.2. Research setting

The Netherlands currently has 16 specialised sexual assault centres that integrate acute medical, forensic and psychological care for recent victims of sexual assault. Four of these centres will participate and collaborate in this study. All these sexual assault centres are located in urban areas. In each centre, a principle investigator, case managers and therapists are involved in carrying out the study. Psychology students conduct the assessments.

2.3. Participants

For this study, rape has been defined as self-reported oral, vaginal or anal penetration without consent. Victims are excluded from the present study if the assault experience that they describe does not comply with this strict definition of penetration. Also, victims are excluded if they do not speak Dutch or are younger than 16 years old. Furthermore, victims who are already receiving trauma-focused treatment or suffer from acute psychosis, substance abuse or suicidal ideation that requires for immediate care are excluded from study participation to prevent interference. Victims with intellectual disabilities (e.g., victims following special education or living in specialised housing facilities) are also excluded. Figure 1 shows the expected eligibility, exclusion, and drop-out of the study. Drop-out is defined as participants who are lost to follow-up. Treatment noncompliance is not considered drop-out when

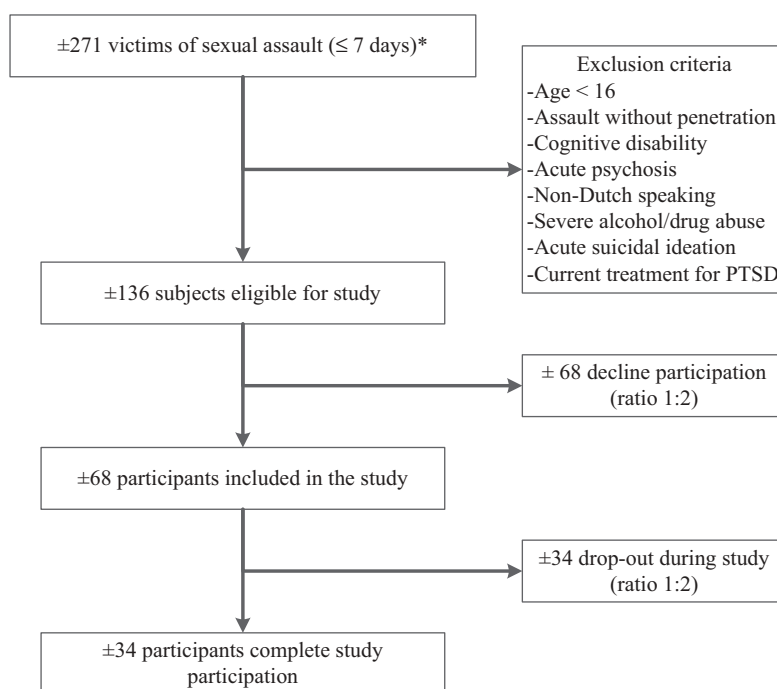
participants are still available for assessments. Dropout rates are modelled after those of Rothbaum et al. (2012), who performed a similar trial.

2.4. Interventions

Subjects who are randomly allocated to the intervention condition will receive two sessions of Early EMDR therapy between 14 and 28 days post-rape. In EMDR therapy, the therapist aims to reduce the vividness and emotionality of trauma memories by asking the patient to recall the trauma memory while simultaneously making eye movements (F. Shapiro, 2017). The Early EMDR protocol slightly varies from the standard eight-phased EMDR protocol (De Jongh & Ten Broeke, 2013; F. Shapiro, 2017) in that it starts with asking subjects to tell the story of the rape until the start of the session (trauma episode narrative) instead of asking for the narrative of the rape itself. This part is adapted from the EMDR Recent Traumatic Episode Protocol (R-TEP; E. Shapiro & Laub, 2008, 2014; E. Shapiro, 2012). Next, the most disturbing mental representation of this trauma memory is identified and the negative cognition (e.g., 'I feel helpless/powerless'), emotions, subjective units of disturbance (SUD), and location of the disturbance related to this target image are assessed. The other adaptation from the standard EMDR protocol is that after the reprocessing of the trauma memory (i.e., when the disturbance related to all target images in this episode is processed to a SUD of zero) the

installation of a positive cognition (e.g., 'I can handle it' or 'I am safe now'), and the 'body scan' are applied over the entire memory from the rape until the EMDR session (Shapiro & Laub, 2008), rather than on the memory of the event itself (F. Shapiro, 2017). After the memory has successfully been resolved, the patient's flashforward (i.e., his or her most horrible fantasy about the future, e.g., being raped again) – if present – will be desensitised to reduce anticipatory fear and avoidance behaviour (De Jongh, 2015; Logie & De Jongh, 2014). This is followed by a Mental Video Check (De Jongh, 2015; F. Shapiro, 2017) to reduce tension or anxiety about future events. During the two sessions, participants will receive a total of three and a half hours of early EMDR from a certified EMDR-therapist who has been trained in the Early EMDR protocol by an EMDR Europe approved trainer. The EMDR therapy will be implemented with the use of rapid deployment of sets of eye movements offered by fingers or using a light bar because this type of tasks has been found the most effective in taxing individuals' working memory in EMDR therapy (De Jongh & Ten Broeke, 2013). No relaxation or emotion regulation skills training was applied prior to the processing of the memories (for the rationale see De Jongh et al., 2016). All EMDR sessions will be videotaped for treatment fidelity analysis by assessors who are blinded to outcome.

The control group will receive treatment as usual, which consists of the Watchful Waiting protocol (National Institute of Clinical Excellence [NICE], 2005).



* Based on annual report 2016 Dutch Rape Centres

Figure 1. Flow chart of estimated subject inclusion.

* Based on annual report 2016 Dutch Rape Centres

This protocol is used in all Dutch Sexual Assault Centres and consists of close monitoring of the patients stress reactions without active treatment. Patients are contacted at least twice between 14 and 28 days post-rape by their case manager and are provided psychoeducation concerning posttraumatic stress symptoms and trauma recovery, as well as emotional support. Furthermore, the standard protocol for Watchful Waiting involves screening of posttraumatic stress symptoms and referral to psychological care if needed. In the interest of the present study, case managers do not screen nor refer. Participants can be referred by the researcher after completing or ending participation, if needed.

2.5. Procedures

Victims of sexual assault can make a self-referral to their local sexual assault centre within seven days post-rape. They can also be referred by the police or other professionals involved (e.g., general practitioners, psychologists, social workers). At admission, victims receive a medical examination and treatment for injuries. They also receive medication to prevent pregnancy and the contraction of sexually transmitted diseases. Subjects who wish to make an official report to the police will do so before the start of the intervention. If so, potential evidence is collected by a forensic medical examination. Furthermore, a personal case manager is assigned to the victim. One day after admission, the case manager contacts the victims to provide them with psychoeducation on normal reactions after rape. During this contact, the case managers will check the inclusion/exclusion criteria for the Early EMDR study. If a victim meets

the inclusion criteria, the case manager will provide the victim with information about the study and a researcher will contact him/her the following day.

One day after inclusion by the case manager, a researcher will contact the victims by telephone. He or she will answer any questions concerning the study and will ask the victim to participate in the study. After verbal consent, the victim will receive an email with an anonymized link to confirm their consent digitally. The subject and the researcher will also sign an informed consent form on paper at the pretreatment assessment. The study was granted approval by the Medical Ethical Committee of UMCU (NL60551.041.17).

2.6. Assessments

Subjects will be assessed at four time points: pretreatment at two weeks post-rape, posttreatment at one week posttreatment, and follow-ups at 8- weeks and 12-weeks post-rape. Assessments consist of questionnaires and two interviews: one on posttraumatic stress symptoms and one on other psychopathology. All assessments will be conducted at the subject's home by a trained psychology student. The time of assessment for each questionnaire and interview can be found in Table 1.

2.6.1. Primary outcome variable

The main study outcome is posttraumatic stress symptom severity, which is assessed using two scales. The Clinician-Administered PTSD Scale for DSM-5 (CAPS-5; Boeschoten et al., 2014) is a structured clinical interview that enables standardised DSM-5 PTSD diagnosis based on symptom severity scores.

Table 1. Assessment instruments.

| Instrument | Type | Construct | Time of assessment |
|---|---------------|---|--------------------|
| Primary outcome | | | |
| Clinician Administered PTSD Scale (CAPS-5) | Interview | PTSD | Post, F1, F2 |
| PTSD Checklist for the DSM 5 (PCL 5) | Questionnaire | PTSD | Pre, Post, F1, F2 |
| Secondary outcomes | | | |
| The MINI International Neuropsychiatric Interview (MINI Plus 5.0.0) | Interview | Comorbid psychopathological diagnoses | Post, F1, F2 |
| Hospital Anxiety and Depression Scale (HADS) | Questionnaire | Severity of general anxiety and depression symptoms | Pre, Post, F1, F2 |
| Brief Symptom Inventory (BSI) | Questionnaire | Comorbid psychopathological symptoms | Pre, F1, F2 |
| Dissociation Tension Scale (DSS) | Questionnaire | Dissociation pattern | Pre, Post, F1, F2 |
| Amsterdam Hyperactive Pelvic Floor Scale for Women (AHPFS-W) | Questionnaire | Pelvic floor functioning | Pre, F2 |
| Female Sexual Functioning Index (FSFI) | Questionnaire | Sexual functioning | Pre, F2 |
| Additional questions on sexual functioning | Questionnaire | Sexual functioning in comparison to before the sexual assault | Pre, F2 |
| (based on Tarquinio et al., 2012) | | | |
| Questions on guilt or shame | Questionnaire | Guilt or shame about the sexual assault | Pre, F2 |
| (based on Foa et al., 1991) | | | |
| Visual Analogue Scale (VAS) | Questionnaire | Trauma image vividness and emotional intensity of the image | Pre, Post, F1, F2 |
| Trauma Memory Questionnaire (TMQ) | Questionnaire | Trauma memory disorganization | Pre, Post, F1, F2 |
| Tonic Immobility Scale (TIS) | Questionnaire | Tonic Immobility | Pre |
| Rape and Mental Health Care History | Questionnaire | Prior rape history and mental health care history | F2 |
| Research participation | | | |
| Reactions to Research Participation Questionnaire Revised | Questionnaire | Research participation | F2 |

Note. Time of assessment is defined as pretreatment (Pre), posttreatment (Post), follow-up assessment at eight weeks post-assault (F1) and follow-up assessment at 12 weeks post-assault (F2).

The standardised interview assesses 20 DSM-5 PTSD symptoms, the subjective distress and impact of the symptoms on social and occupational functioning on a scale from 0 (absent) through 4 (extreme/incapacitation). Because all subjects in the present study suffered rape, the interviewer does not assess Criterion A (identification of traumatic event). The CAPS-5 version for the past week is used at the posttreatment assessment. The version for the past month is used at both follow-ups. High validity and reliability of the CAPS-5 have been found in a sample of military veterans (Weathers et al., 2018).

Because the CAPS-5 cannot be used at pretreatment assessment of posttraumatic stress symptoms in the present study, severity of these symptoms is also indexed using the PTSD Checklist for the DSM-5 (PCL-5; Boeschoten, Bakker, Jongedijk, & Olff, 2014) at each assessment. This is a 20-item self-reported questionnaire on symptoms of PTSD that is scored on a 5-point Likert scale from 0 to 4. Subjects answer the questions, such as 'repeated, disturbing dreams of the stressful experience', based on the past week at pretreatment and posttreatment and based on the past month at follow-ups. A previous study on trauma-exposed college students found strong internal consistency, test-retest reliability, convergent validity and discriminant validity of the PCL-5 (Blevins, Weathers, Davis, Witte, & Domino, 2015).

2.6.2. Secondary outcome variables

2.6.2.1. Psychological functioning. MINI International Neuropsychiatric interview Plus (MINI Plus; Van Vliet, Leroy, & Van Megan, 2000) is a structured clinical interview that enables standardised DSM diagnosis of depression, suicide ideation, (hypo) manic disorder, social anxiety, generalised anxiety disorder, obsessive-compulsive disorder, alcohol dependency, drug dependency, psychotic disorders, eating disorders, somatization disorders, and attention deficit and hyperactivity disorder. For each diagnosis, the interviewer asks questions about symptoms that are answered as 'yes' or 'no'. This interview is used at posttreatment and both follow-up assessments. The MINI Plus is the extended version of the MINI: A structured, well-validated diagnostic interview that assesses diagnostic criteria of the DSM-IV (Van Vliet & De Beurs, 2006).

For further assessment of psychological functioning, three questionnaires are used. First, the Brief Symptom Inventory (BSI; De Beurs, 2004) is a 53-item questionnaire on psychological symptoms during the last week that is scored on a 5-point Likert scale from 0 to 4. The scores generate nine subscales and a score for total symptoms. The BSI is used at pretreatment and both follow-ups. Previous research found good internal consistency and test-retest reliability (De Beurs & Zitman, 2006).

Second, the Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983) is used to provide additional information on depression and anxiety. The HADS is a 14-items questionnaire on symptoms of anxiety and depression during the last week and is scored on 4-point Likert scale from 0 (never) to 4 (almost always). The HADS is used at every assessment. Internal consistency and test-retest reliability were estimated as good (Spinoven et al., 1997).

Third, the Dissociation Tension Scale (DTS; Stiglmayr et al., 2010) scores the presence of dissociation during the last week at each assessment. Subjects answer 21 items on a scale of 0 to 100, with 0 meaning not present and 100 meaning constantly present. Previous research shows high internal consistency and good convergent, discriminant, and differential validity (Stiglmayr et al., 2010).

2.6.2.2. Sexual functioning. Three questionnaires are used to assess sexual function at pretreatment and last follow-up. First, the Amsterdam Hyperactive Pelvic Floor Scale (AHPFS; Van Lunsen & Van Laan, 2007) is 30-item questionnaire on pelvic floor problems, reported on a 5-point Likert scale from 0 (never) to 4 (always). The psychometric qualities of this questionnaire have not yet been published.

Second, the Female Sexual Function Index (FSFI; Rosen et al., 2000) scores sexual desires, arousal, and penetration during the last month using 19 items on a 5-point Likert scale. The internal consistency and discriminant validity of the FSFI are high (Wiegel, Meston, & Rosen, 2005).

Third, two items from the study of Tarquinio et al. (2012) are used to determine post-rape sexuality: 'Would you say that your level of desire or interest in your sex life is comparable to what it was before the sexual violence?' and 'Would you say that your level of sexual stimulation (or excitation) is comparable to what it was before the sexual violence?' Items are scored on a 5-point Likert scale.

2.6.2.3. Guilt/shame. Two items from the study of Foa, Rothbaum, Riggs, and Murdock (1991) are used to determine guilt and shame about the rape at pretreatment and the last follow-up: 'During the last week, did you feel guilty about the traumatic event?' and 'During the last week, did you feel shame about the traumatic event?'. Both are scored on a 5-point Likert scale from 0 (never) to 4 (always).

2.6.2.4. Image vividness and emotional intensity. Two VAS items were created to measure image vividness and emotional intensity after a 10 second recall of the most disturbing image of the rape. These items are used as process measures of the early EMDR intervention. The questions are 'How vivid was the image of the memory?'

scored from not vivid through very vivid, and ‘how unpleasant was the image of the memory?’ scored from not unpleasant through very unpleasant (Van Veen et al., 2015). Subjects score image vividness and emotional intensity on the same image during every assessment.

2.6.2.5. Trauma memory disorganisation. Trauma Memory Questionnaire (TMQ; Halligan, Michael, Clark, & Ehlers, 2003) is a nine-item questionnaire that scores the ability to remember the recent trauma on a 5-point Likert scale. This questionnaire is used at every assessment.

2.6.2.6. Tonic immobility. The Tonic Immobility Scale (TIS; De Kleine, Van Minnen, & Hagenaars, 2009; Forsyth, Marx, Fusé, Heidt, & Gallup, 2000) is a questionnaire on the severity of peritraumatic tonic immobility. The first part consists of 12 items that are scored on a 7-point Likert scale. This part is measured at every assessment. The second part of the questionnaire indexes assault characteristics and is not used in the present study. Strong internal consistency of the TIS has been found in a sample of female sexual assault victims (Fusé, Forsyth, Marx, Gallup, & Weaver, 2007).

2.6.2.1. Rape and mental health care history. A nine-item questionnaire was developed to determine the subjects’ sexual assault history (e.g. ‘Have you ever experienced sexual assault, prior to the last assault’), mental health care history (e.g. ‘Have you even had trauma-focused therapy prior to your participation to this research’), and consciousness during the assault. All questions are dichotomous yes/no variables and are assessed at the last follow-up.

2.6.3. Research participation

To monitor the subjects’ opinions and assumptions about research participation, the Reactions to Research Participation Questionnaire – Revised (RRPQ-R; Newman, Willard, Sinclair, & Kaloupek, 2001) is used at the end of the last follow-up. This questionnaire contains of 23 items on personal satisfaction, personal benefits, emotional reactions, perceived drawbacks and global evaluation of participation to the research. The items are scored on a 5-point Likert scale. Although a validation study on the RRPQ-R has not been published, the versions for children and parents show adequate internal consistency (Kassam-Adams & Newman, 2002).

2.7. Power and sample size calculation

Power calculation methods are not available for mixed model procedures. We thus used a power calculation for repeated measures (within x between design) as a conservative approximation.

For a 2 between (treatment conditions) x 2 within (pretreatment, posttreatment) repeated measures ANOVA ($\alpha = .05$, power = .80, correlation between measures = .5, and medium effect-size $f = .25$), a total sample size of $N = 34$ will be required (G power; Faul, Erdfelder, Lang, & Buchner, 2007).

2.8. Data analysis

A linear mixed model analysis will determine the difference between the intervention group and control group in changes in posttraumatic stress symptom severity and other psychopathology over time. Intention-to-treat analyses will test the main effect of treatment condition, the main effect of time, and the interaction effect. Completers analysis will be used for comparison, but due to the expected high drop-out rates, this analysis is possibly biased. The assumptions of normality, homogeneity of variances, and sphericity will be tested prior to interpreting the results.

3. Discussion

The current study will be the first RCT that examines the effectiveness of early EMDR intervention compared to treatment as usual in reducing posttraumatic stress symptoms in rape victims. This is of importance given that sexual assault victims suffer from a broad spectrum of psychological and sexual dysfunctions (Galatzer-Levy et al., 2013). Furthermore, many victims of sexual assault develop posttraumatic stress symptoms (Elklit & Christiansen, 2010; Rothbaum et al., 1992) which has been found to increase the risk of revictimization (Messman-Moore et al., 2009).

For the purpose of the present study an early EMDR treatment protocol was developed that not only closely resembles the Standard EMDR protocol (F. Shapiro, 2017) and the R-TEP protocol (E. Shapiro & Laub, 2008) but also entails the reprocessing of patients flash-forwards when these are present (Logie & De Jongh, 2014), and the application of the Mental Video Check (De Jongh, 2015; F. Shapiro, 2017). Further strengths are that the protocol can be completed in two treatment sessions, and that the study uses a broad variety of secondary outcome measures which includes psychological and sexual functioning, and guilt/shame. Another advantage is the use of a randomised pretest-posttest controlled design that will limit selection bias and detection bias by randomised sequence generation, allocation concealment and blinding of outcome assessment (Higgins & Green, 2011).

Some limitations of the present study design should also be noted. First, a waitlisted control group was not deemed ethical as almost all victims of sexual assault experience immediate posttraumatic stress (Elklit & Christiansen, 2010; Rothbaum et al., 1992). Therefore, the present study compares early EMDR intervention to

treatment as usual (i.e. Watchful Waiting; NICE, 2005). This design precludes any statements of the added value of early EMDR intervention over no treatment. Second, an argument of natural recovery can be made: Although most victims experience posttraumatic stress immediately post-rape, more than half of them recover after three months (Elklit & Christiansen, 2010; Rothbaum et al., 1992). Unfortunately, predictors for natural recovery after rape have not yet been identified and could therefore not be measured at baseline. Therefore, the present study is likely to treat victims who would not have developed PTSD anyway. However, as victims are randomly allocated over the two interventions, natural regression is unlikely to affect study results. Moreover, the victims who recover from the posttraumatic stress after three months might still develop delayed-onset PTSD (Andrews, Brewin, Philpott, & Stewart, 2007). Thus, early intervention can still be clinically relevant for these victims.

In conclusion, the results of this RCT are a first step into developing evidence-based preventative treatment for PTSD after rape, which in turn might prevent the vicious cycle of rape, PTSD, and revictimization.

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